AGENCY PARTNER COMMITTEE RECOMMENDATIONS FOR LABORATORY ACCREDITATION STANDARDS

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SUMMARY

- Held Our Third Meeting on July 5, 2016
- Reviewed ELTAC's Comments on Regulatory Agency Needs
 - Kept questions and issues in mind as we progressed
- Discussed the Three Elements of Laboratory Accreditation
 - Technical Standards
 - Proficiency Testing Samples
 - Quality Management Systems
- Developed Recommendations Regarding Accreditation
 Standards

TECHNICAL STANDARDS

- California Should Maintain Own List of Approved Methods and Method Requirements
 - Fields of Testing updated regularly
 - Formal announcement to laboratories prior to update
- Short Term: List Should be Generated by Agency Partners
 - Meet regulatory needs
 - Try to keep versions out of regulations when possible
- Longer Term: List Should be Expanded to Address Method Requests
 - ELTAC will know of Agency Partner needs not covered
 - Agency has option to disallow methods

PROFICIENCY TESTING SAMPLES

- One Proficiency Testing Sample Per Year is Adequate
- Rationale: Agency Partners have a Low Opinion of PT Sample
 System
 - Laboratories game the system
 - Not a true reflection of laboratory performance
 - Don't see value in doing multiple samples per year
- Long Term: Interact with ELAP to Improve System

PROFICIENCY TESTING SAMPLES (CONT.)

- Steps to Improve System
 - Make Samples Truly Blind Samples
 - Increase Complexity of Sample Matrix
 - Conduct Laboratory Intercalibrations Using Truly Blind Samples
- Supportive but Feel Lower Priority/Longer Term Project

QUALITY MANAGEMENT SYSTEMS

- Requirement
 - Need for confidence in data
 - Unanimous response
- Fueled by Lack of Confidence in Other Two Inspection Elements
 - Technical standard/requirements method modifications,
 incorrect application, audit gives us snap shot
 - Monitoring requirements PT samples can be gamed and the current system is not robust
- A quality management system must be present in order to meet our regulatory agency needs

QUALITY MANAGEMENT SYSTEM (CONT.)

- Our Recommendation: The NELAC Institute (TNI)
 - Dissention expressed by Fish And Wildlife Agency
- Multiple reasons:
 - Ready for adoption as is concerned that writing our own or modifying another state's will take too long
 - Clear, consistent standard for auditing purposes
 - Updated regularly, sustainable standard
 - Current training and implementation resources available
- Big Change; Suggest a Phased Implementation

PHASED IMPLEMENTATION

- Quality Management System Sections can be Prioritized
- Work with ELTAC to Prioritize Those Elements to be Implemented Within First Year
- Work with ELTAC to Identify Elements that can have a Multi-Year Phase-in
- Not Requiring CA Labs to be TNI Accredited but Use Tools
- Possible Starting Point Towards Developing Own Guidance

